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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/867,948  | 05/30/2001  | Brian Maiorella      | PP00693.104         | 9747             |
| 7590  | 12/22/2003  |                      | EXAMINER            |                  |
| Chiron Corporation<br>Intellectual Property<br>P.O. Box 8097<br>Emeryville, CA 94662-8097 |             |                      | LIU, SAMUEL W       |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1653                |                  |
| DATE MAILED: 12/22/2003   |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/867,948             | MAIORELLA ET AL.    |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Samuel W Liu           | 1653                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 October 2003.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 3-6 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 000203.                    6) Other: \_\_\_\_\_

## **DETAILED ACTION**

The response filed 6 October 2003, which amends claim 6, has been entered. The following pending claims 1 and 3-6 are examined in this Office action.

Note that the grounds of objection and/or rejection not explicitly stated and/or set forth below are withdrawn.

*The following is the new ground of rejection*

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-6 are rejected under 35 U.S.C. 102 (b) as being anticipated by Reuveny, S. et al. (*J Immunol Methods*. (1986, January) Vol. 86, pages 53-59).

Reuveny et al. teach a process of determining the optimal level of a product (i.e., monoclonal antibodies, McAb) production in animal cell culture (e.g., hybridoma cell lines) wherein the solute, e.g., 25% of dissolved oxygen (DO) in a culture medium, has an inhibitory effect on cell viability and optimal growth when compared to normal 60% OD (see the right column at page 55, the left column at page 56, and Figure 2).

Reuveny et al. teach monitoring the McAb production as the varied DO percentages (see page 55, the right column, and , “Material and methods” section), wherein the McAb production increases under 25% DO in comparison with normal

condition of 60% DO as illustrated in Figure 2; this increase is at least 50 % (see abstract).

Further, Reuveny et al. teach selecting the DO 25%for optimal combination of cell growth and product expression (see abstract and Figure 2).

The above Reuveny et al. teachings meet the limitations set forth in claims 1, 3-4 and 6of the current application. Since said MaAb is IgG (see page 53, the right column), the Reuveny et al. teachings also anticipate the application claim 5.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

*swl*

Samuel W. Liu, Ph.D.

December 5, 2003

*Karen Cochrane Carlson*

KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER